K041849

JUL 2 1 2005

COOK

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510(k) Summary

Submitted by:	COOK INCORPORATED 750 Daniels Way, PO Box 489 Bloomington, IN 47402-0489
Contact Person:	Earl E. Knight III, MPA Regulatory Affairs Ph: (812) 339-2235 Fax: (812) 332-0281
Date Prepared:	July 15, 2004
510(k) #:	**K041849**
Device:	
Trade Name:	Turbo-Flo® PICC
Common/Usual Name:	Peripherally Inserted Central Venous Catheter
Proposed Classification:	Percutaneous, Implanted, Long-Term Intravascular Catheter 21 CFR Part 880.5970 (80 LJS) Class II

Device Description:
Turbo-Flo® PICCs are polyurethane peripherally inserted central venous catheters 60 cm in length, available in 4 & 5 Fr single lumen and 5 Fr double lumen for short and long-term use. Catheters are inserted using an obturator version or an over-the-wire version.

Intended Use:
Turbo-Flo® Peripherally Inserted Central Venous Catheters (PICC) are indicated for short or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The maximum pressure setting/limit of power injectors used with the Turbo-Flo PICC may not exceed 300 psi for the 5 Fr single lumen and 200 psi for the 4 Fr single lumen and 5 Fr double lumen. The Turbo-Flo PICC is indicated for a single injection of contrast media through a power injection.

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Substantial Equivalence:

Manufacturer	Device	510(k) #
Cook Incorporated	Urethane PICC Line (Turbo-Flo®)	K992198
Cook Incorporated	Double Lumen Urethane PICC (Turbo-Flo®)	K010034
CR Bard	PowerPICC™ Catheters	K033389

In terms of section 510(k) substantial equivalence, the Turbo-Flo® PICC is similar in terms of material design, intended use and technological characteristics to predicate intravascular catheters for short or long-term use.

Test Data:

The Turbo-Flo® PICC has undergone testing which provide reasonable assurance of safety and effectiveness for its intended use equivalent to predicate devices. Testing included tensile, flow rate, leakage, stability, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2005

Cook Incorporated
Earl E. Knight III, MPA
750 Daniels Way P.O. Box 489
Bloomington, Indiana 47402

Re: k041849
Trade/Device Name: Turbo-Flo PICC
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 21, 2005
Received: April 22, 2005

Dear Mr. Knight:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the **Warnings** section of the devices' labeling:

> The safe and effective use of the 4 Fr Single Lumen and 5 Fr Double Lumen Turbo-Flo PICC catheters with power injector pump pressure settings above 200 psi has not been established.

Please note that the above labeling limitation is required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before this limitation is modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as

described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-___. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K041849

Device Name: Turbo-Flo® Peripherally Inserted Central Venous Catheter

Indications for Use:

Turbo-Flo® Peripherally Inserted Central Venous Catheters (PICC) are indicated for short or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The maximum pressure setting/limit of power injectors used with the Turbo-Flo PICC may not exceed 300 psi for the 5 Fr single lumen and 200 psi for the 4 Fr single lumen and 5 Fr double lumen. The Turbo-Flo PICC is indicated for a single injection of contrast media through a power injection.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Suzette Y. Frilette (M.D.)
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041849